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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,841	02/20/2004	Masato Horie	Q-76526	5773
23373 7590 02/06/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER WHITEMAN, BRIAN A	
			ART UNIT 1635	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/06/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/781,841

Applicant(s)

HORIE, MASATO

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/7/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 30-33 are pending.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 11/7/06 is being considered by the examiner. The IDS was submitted before the first office action and applicant was supplying the authors of the articles listed on the IDS, but not considered because they were missing the author's name.

#### ***Claim Rejections - 35 USC § 101 and 35 USC § 112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-33 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by a substantial or well-established utility.

The instant specification contemplates that the novel human NRP1 gene is provided and the use of said gene makes it possible to detect the expression of said gene in various tissue and product the human NRP1 protein by the technology of genetic engineering. NRP1 can further be to study in brain neurotransmission system, diagnosis of various diseases related to

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neurotransmission in the brain, and the screening and evaluation of drugs for the treatment and prevention of such diseases (page 90-91). The NRP might be secretory proteins or proteins anchored to membranes as a result of posttranslationation modification (page 89). The applicant speculates that NRP might function as ligands by stimulating other molecules such as EGF receptors (page 89). Furthermore, the EGF-domain containing NRP could act as growth factors in brain and may be useful in the diagnosis and treatment of various kinds of intracerebral tumor and effective in nerve regeneration in cases of degenerative nervous diseases (page 91). The domains of NRP suggest that NRPs might play a role as signal molecules for growth regulation (page 90). Applicant further suggests that these genes might have particular function in kidney (page 90).

The claims are drawn to an isolated nucleic acid molecule encoding a nel-related protein type 1 (NRP1, also known as NELL1) consisting of the DNA sequence in SEQ ID NO: 35. At the time the invention was made, it was unknown that SEQ ID NO: 35 or a nucleic acid sequence encoding SEQ ID NO: 34 were associated with a role in having cranial nerve growth activity and/or nerve regenerating activity. The instant specification does not teach what activity is related with expression of NRP1. The instant specification provides no nexus between the 'association' of the claimed nucleic acid molecule with cranial nerve growth and/or nerve regeneration.

With respect to using the claimed polynucleotides or products made directly or indirectly from the nucleic acid molecule in either an *in vitro* or an *in vivo* screening assay comprising observing an increase or a decrease of the claimed DNA products or NRP1-associated gene products, the instant specification does not teach what to look for as a result of an increase or a

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decrease in expression of SEQ ID NO: 34 encoded by a DNA sequence or a polynucleotide comprising SEQ ID NO: 35. One skilled in the art would have to further experiment on the invention to determine what results are observed with either an increase or a decrease in expression of SEQ ID NO: 34 in a genus of cells, including neurons (nerve cells). In absence of the instant specification teaching what to look for in the assays, the claimed invention lacks utility.

In addition, with respect to using the claimed nucleic acid molecule or products made directly or indirectly from the sequences, the instant specification provides no evidence that SEQ ID NO: 35 or a nucleic acid encoding SEQ ID NO: 34 is involved in intracerebral tumor or degenerative nerve diseases. The specification provides no evidence that the claimed DNA sequences are associated with any specific disease (e.g., tumor, kidney disease, degenerative nervous disease). It would require further experimentation on the claimed invention/or products made directly or indirectly from the DNA sequences to determine whether they were involved in intracerebral tumor or other disease(s). Thus, the asserted utilities set forth above do not provide a benefit to the public in currently available form. See *Ziegler*, 992 F.2d at 1203, 26 USPQ2d 1600 (Fed. Cir. 1993).

At pages 88-89 of the specification, the applicant teaches the result of homology analysis for NRPs and nel. The applicant and prior art teach that NRP1 has 50% homology to chick embryonic nel (page 88). NRP1 is considered not to be a human counterpart of nel, but a homologous gene (page 89). The domains of NRP suggest that NRPs might play a role as signal molecules for growth regulation (page 90). The instant specification and the prior art are absent for an undefined NRP protein having several EGF-like repeats. The skilled artisan understands

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that EGF repeats are present in several proteins with different functions. At page 90, applicant teaches that Northern blot analysis, it was found that NRP1 was weakly expressed in fetal and adult brain and kidney. The office conducted a sequence search of the polynucleotide sequence set forth in SEQ ID NO: 35 against nucleotide public databases. The results from the polynucleotide sequence databases search did not display any sequence similarity with any known gene associated with cranial nerve growth and/or nerve regenerating activity. Sequences, at the time the application was filed, with the closest sequence similarity with SED ID NO: 35, besides nel, is fibrillin I, 11.7% identity (calcium-binding protein). Furthermore, a post-filing reference teaches that the precise role of Nell-1 is unknown (see Ting et al. Journal of Bone and Mineral Research, 14:80-89, 1999).

Since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. See also *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967) and *In Brenner v. Manson*, 383 US 519, 148 USPQ 689 (1966). Also see REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS: [www.uspto.gov/web/menu/utility.pdf](http://www.uspto.gov/web/menu/utility.pdf).

Applicant's arguments filed 11/7/06 have been fully considered but they are not persuasive for the following reason(s):

The Declaration under 37 CFR 1.132 filed 11/7/06 is insufficient to overcome the rejection of claims 30-33 based upon 101 rejection as set forth in the last Office action because: the product (rat NPR1) tested by applicant is not the product recited in the instant claims. The applicant states that rat NPR1 DNA has about 93% homology to human Nell1 DNA. The applicant does not indicate if the Nell1 DNA in Kang is the DNA recited in the instant claims.

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The skilled artisan understands that even one nucleotide change in a polynucleotide sequence or one amino acid change in a polypeptide sequence can change the function of the protein. See Lucentini, *The Scientist*, 18:20, 2004. Thus, the skilled artisan would not be able to reasonably extrapolate from the teaching in the specification to the activity of the rat NRP1 protein.

Claims 30-33 remain also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed 11/7/06 have been fully considered but they are not persuasive for the reasons set forth under the 101 rejection.

### ***Response to Arguments***

Applicant's arguments, see page 4, filed 11/7/06, with respect to 102(a) have been fully considered and are persuasive. The rejection of claim 30 has been withdrawn because the applicant has filed a certified translation of the foreign priority documents.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Schultz, PhD, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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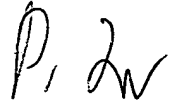
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Brian Whiteman

A handwritten signature in black ink, appearing to read 'B. W.' or similar, located below the printed name 'Brian Whiteman'.